FSIS BACKGROUNDER

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Clenbuterol

The U.S. Department of Agriculture's Food Safety and Inspection Service is responsible for ensuring that meat and poultry products are safe, wholesome and accurately labeled. The Agency works in cooperation with the Food and Drug Administration, which is mandated to ensure the safety of all other food products and is responsible for regulating animal drugs and feedstuffs.

Illegal Use

In 1991, FDA and FSIS were alerted that the illegal veterinary drug clenbuterol was being used to gain competitive advantage in some show animals such as calves, lambs, and swine. According to USDA officials, show animals comprise less than one percent of the millions of food animals slaughtered in the United States. Nevertheless, the illegal use of clenbuterol could be a public health concern if show animals were to be slaughtered for human food with clenbuterol residues in the liver or in the muscle tissue (meat).

Clenbuterol residues can affect lung and heart function in persons who have eaten liver or meat of animals given the drug. In the United States, no human illnesses have been associated with clenbuterol use in food animals. But, several outbreaks of reversible, short-term illnesses in Europe have been traced to ingesting clenbuterol residues in European beef liver.

To protect the public health, FSIS and FDA are taking enforcement actions against the illegal use of clenbuterol in show animals. While, FDA takes regulatory action against persons involved in the use or distribution of clenbuterol, FSIS tests meat and liver for illegal residues to help keep contaminated meat out of consumer channels. FSIS and FDA coordinate findings with the Justice Department, which handles prosecution of violators of Federal law.

At the same time, FSIS and FDA are working with other organizations to educate the agricultural community about the public health concern and the legal risks. Groups include the Extension Service, producer organizations, state officials, the Future Farmers of America, the 4-H, and livestock show leaders.

Background

Clenbuterol is a growth-promoting drug in the beta-agonist class of compounds. It is not a hormone. Its illegal use in show animals is linked to its ability to induce weight gain and a greater proportion of muscle to fat. It is not licensed for any use in the United States, but some countries have approved it for use in animals not used for food, and a few countries have approved it for therapeutic uses in food producing animals. The dosages needed for therapeutic purposes are much lower than those required to increase muscle mass. Clenbuterol may be available in the United States through chemical supply houses for laboratory use and the so-called "black market." When used illegally, it is added to animal feed.

Since the first alert in 1991, USDA and FDA have been working with state departments of agriculture and others to avoid contamination of the meat supply. The agencies have alerted them about possible illegal use of clenbuterol. FDA also alerted U.S. Customs to block the illegal import of clenbuterol and is following up with enforcement activities.

For example, in 1994, traces of clenbuterol residues were found in animals at stock shows held in Ohio and Oklahoma. In Tulsa, a clenbuterol test of champion animals disqualified six animals including steers, sheep, and a hog. In 1995, two champion steers were disqualified because residues were found at the National Western Stock Show in Denver. FDA is also undertaking investigations concerning the sale of feed with clenbuterol and its possible use in veal calves in several states.

Health Concerns

No deaths were reported in several European incidents involving the consumption of liver with clenbuterol residues. Spain reported two outbreaks of illness in 1990 in 135 persons who consumed contaminated beef liver. Samples had clenbuterol concentrations of 160 to 291 parts per billion. The people were hospitalized with reversible symptoms of increased heart rate, muscular tremors, headache, nausea, fever, and chills.

Clenbuterol was suspected, but not confirmed, as the cause of an earlier outbreak of illness, also in Spain. A similar incident with 22 cases, also traced to beef liver, was reported from France. Clenbuterol was also a concern in Ireland in 1991.

Although the toxic effects of clenbuterol residues have been described as mild, FDA considers all unintended effects on humans to be unacceptable. FDA said it is possible that persons being treated with adrenergic agents or who are otherwise sensitive to these drugs, may be far more severely affected by residues of clenbuterol than are normal, healthy individuals.

FDA is also concerned that the illicit use of clenbuterol could lead to illness or death in persons handling the drug. FDA said it is possible that clenbuterol effects on the cardiovascular system may be more hazardous via occupational inhalation exposure than via ingestion in food. But FDA said it has not been able to confirm reports of such reactions.

Clenbuterol Program

In 1991, FSIS announced it would condemn meat that tests positive for clenbuterol residues. When an animal shows a positive clenbuterol urine screening test, the animal is identified for tracking during transport to slaughter plants. At the plant, the carcasses are held for FSIS testing, as are carcasses from all animals suspected of having illegal drug residues. FSIS inspectors collect liver and muscle tissue samples and send them to the FSIS Midwestern Laboratory in St. Louis for analysis. Testing is done using an FSIS-developed test for clenbuterol in liver. The test is sensitive to one part per billion (1 ppb).

Also, both eyes from the carcass are sent to an FDA laboratory for testing of the retinas. Although the eyeballs are not used to make disposition of retained carcasses, they are extremely helpful in assisting FDA in identifying and investigating violators because residues can remain in the retinas for months.

In addition to testing carcasses after live animals have tested positive at shows, FSIS expanded testing for clenbuterol in 1994 to include an exploratory two-tier program. In Tier I, for one year, FSIS collected and tested more than 1,800 tissue samples taken at random from normal animals (not necessarily show animals). At the end of Tier I testing, in early 1995, there were no positive findings. During Tier II, FSIS samples show animal carcasses at the slaughter plant. Tier II is ongoing and targets approximately eight show animals in each of the agency's five regions every month.

Clenbuterol Testing

Clenbuterol begins to show in the urine and body organs within a day of administration and can remain in the liver for several days. Because the body begins eliminating the drug immediately, it is possible for residues to be depleted from urine and edible tissues if sufficient time elapses before slaughter. But, exposure can be detected by testing retinal tissue from the eyes because residues remain there for at least five months. Retina testing has revealed residues in show animals in Ohio, Oklahoma, and Colorado.

Local Action Is Essential

Prevention of clenbuterol residues in human food from show animals is most effective at the source, which is at the time of sale or administration of the illegal drug. State regulations for residue testing of show animals vary widely. For example, the State of Texas requires testing of show animals at fairs and livestock shows for antibiotics, hormones, diuretics, and steroids. Beta-agonists are also included, but other states may not have such regulations.

To help stop use of clenbuterol in show animals and other livestock used for food, since 1991 FSIS, FDA, and USDA's Extension Service have been working with others, including state agriculture and inspection officials, slaughterhouse managers, as well as leaders of livestock shows, 4-H groups, and the Future Farmers of America.

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